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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,774	04/14/2004	David B. Phillips	05610.0002.NPUS00	4706

22930 7590 07/17/2006

HOWREY LLP
C/O IP DOCKETING DEPARTMENT
2941 FAIRVIEW PARK DR, SUITE 200
FALLS CHURCH, VA 22042-2924

EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,774	PHILLIPS, DAVID B.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *17-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 17-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (group II), there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 22 May 2006.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sage, Jr. (U.S. 5,256,137) or Haak et al (U.S. 6,317,629) in view of Tapper et al (U.S. 4,340,047). Regarding claims 1 and 6, Sage discloses (col. 3, lines 14-20) an iontophoretic drug delivery system that includes a device having a drug reservoir and an electrolyte reservoir that are "adapted to be placed in communication with the skin of an animal." The device includes two electrodes wherein "the first electrode may be mounted at least partially in the drug reservoir, and the second electrode may be mounted at least partially in the electrolyte reservoir." The examiner considers this to be a first container and a second container that are configured to hold a fluid, and a first and second electrode that are configured to be in electrical contact with the fluids contained in the reservoirs. Sage also discloses (col. 3, lines 26-31) a

biphasic power source that "preferably includes a constant current source having two outputs connected to the electrodes of the drug delivery device, and a voltage limiting circuit, such as a zener diode, coupled in parallel with the outputs of the constant current source to limit the voltage across the electrodes to a predetermined voltage." The examiner considers this to be a controller that is configured to output a signal, and a first and second electrode configured to be coupled to the controller, and configured to receive the signal output from the controller.

4. Haak discloses (col. 5, lines 43-45) a drug delivery or electrotransport system comprising a device (10), in which a donor electrode (22) is positioned adjacent a drug reservoir (24) while a counter electrode (23) is positioned adjacent a return reservoir (25) which contains an electrolyte. The device also has an electric circuit (32; col. 5, lines 5-20) which includes "control circuitry such as a current controller" and one or more electronic components which "control the level, waveform, shape, polarity, timing, etc of the electric current applied by the device." The examiner considers this to be a controller, a first and second container configured to hold a fluid, and a first and second electrode configured to be in electrical contact with the fluid in the containers and coupled to the controller.

5. Sage and Haak fail to teach an asymmetrical biphasic output signal. Tapper however discloses (col. 2, lines 55-65; Figure 1) direct current applied topically to the skin by a pair of electrodes. This current includes a treatment portion (14) of the waveform (12) that is "periodically interrupted by a relatively short pulse (16) of current in the opposite direction in order to prevent the formation of undesirable vesicles, bulla

or redness of the user's skin in the treated area." Tapper, Haak and Sage all teach iontophoretic application of current to the skin of a patient using electrodes. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Haak's or Sage's waveform output with Tapper's asymmetrical biphasic signal in order to reduce irritation in the skin due application of an electric stimulation signal to the patient.

6. Regarding claim 2, Tapper discloses (col. 3, lines 60-65) a transformer (22) having a primary and a secondary winding, for providing a steady flow of unidirectional current across the electrodes.

7. Regarding claim 3, Haak discloses (col. 5, lines 49-55) "reservoirs (24 and 25) can be polymeric matrices or gel matrices adapted to hold a liquid solvent. Aqueous-based or polar solvents, especially water, are generally preferred when delivering agents across biological membranes such as skin. When using an aqueous-based solvent, the matrix of reservoirs is preferably comprised of a water retaining material and is most preferably comprised of a hydrophilic polymer such as a hydrogel."

8. Regarding claims 4-5, Haak discloses (col. 6, lines 9-15) "the drug reservoir (24) contains a neutral, ionized, or ionizable supply of the drug or agent to be delivered and the counter reservoir (25) contains a suitable electrolyte such as, for example, sodium chloride, potassium chloride, or mixtures thereof."

9. Regarding claim 7, Sage discloses (col. 4, lines 11-16; Figure 2) that drug reservoir (21) and electrolyte reservoir (23) are part of a common housing (27).

10. Regarding claim 8, the examiner considers that electrically isolated the first and second electrode from the power source would teach away from delivering the asymmetric biphasic signal to the electrodes. The electrodes are isolated from each other in both the Sage and the Haak reference. The examiner also considers the transformer of Tapper to be capable of isolating the circuitry from the patient, as explained in paragraph 0049 of the present application.

11. Regarding claims 9 and 16, Sage in view of Tapper discloses the claimed invention but does not disclose expressly the output signal is 7.83 Hz. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the frequency of the output signal as taught by Tapper, with the frequency of 7.83 Hz, because the applicant has not disclosed the frequency provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the output signal as taught by Tapper, because Tapper discloses an asymmetric biphasic signal for application to the skin of a patient. Therefore, it would have been an obvious matter of design choice to modify Sage in view of Tapper to obtain the invention as specified in the claims.

12. Regarding claim 10, Tapper discloses (col. 4, lines 8-14) "when a load (30) is imposed across the electrodes (10), a steady flow of direct current is permitted to flow from the battery (20) through the primary winding (24), the diode (28), the secondary winding (26), the load (30), and to ground through a variable resistor (32). The variable resistor is used to control the amount of current which is permitted to flow across the

load." The examiner considers this to be adjusting a voltage associated with the asymmetric biphasic signal based on the resistance between the electrodes.

13. Regarding claims 11-12 and 14, in view of the structure as disclosed by Sage in view of Tapper, the method of operating or using the device would be obvious because it is the normal and logical means by which the device can be used.

14. Regarding claim 13, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sage, Jr. (U.S. 5,256,137) or Haak et al (U.S. 6,317,629) in view of Tapper et al (U.S. 4,340,047) and in further view of Ostrow (U.S. 5,983,134). Sage, Haak and Tapper all fail to teach propagating the output signal through a first extremity and a second extremity. Ostrow however discloses (col. 6, lines 65-68) an electrically conductive applicator pad capable of passing a slow drip liquid drug medium through the skin and surface tissues. The pad forms a cuff that wraps around a body part or limb, and is capable of drug delivery and TENS (transcutaneous nerve stimulation) using iontophoretic and electromagnetophoretic protocols. Ostrow further discloses (col. 5, lines 14-18) "the multi-modal nature of this apparatus covers a broad spectrum of treatment protocols, including the treating of injuries to soft tissues, as well as arthritis of joints at selected locations of the human and mammalian bodies." Sage, Haak, Tapper and Ostrow all teach iontophoretic stimulation systems for applying a drug and an electric current to the skin of a patient. Therefore it would have been obvious to one of

ordinary skill in the art at the time of the invention to modify Sage's or Haak's dual reservoir-electrode system with Tapper's biphasic signal and with Ostrow's limb application in order to provide a reduced-irritation electrical signal to treat arthritis or other injuries to soft tissues.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Deborah L. Malamud
Patent Examiner
Art Unit 3766